

Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.203 Definitions.

As used in this subpart:

(a) *Antifungal*. A drug which inhibits the growth and reproduction of fungal cells and decreases the number of fungi present.

(b) *Athlete's foot*. An infection of the feet caused by certain dermatophytic fungi.

(c) *Dermatophyte*. A fungus that invades and lives upon the skin or in the hair or nails.

(d) *Fungus*. Any of a large division of plants, including dermatophytes, yeasts, and molds, characterized by a simple cell structure and the absence of chlorophyll.

(e) *Jock itch*. A chronic and recurrent infection caused by certain dermatophytic fungi; affects the upper, inner thighs and sometimes extends to the groin and the pubic area; the condition most frequently occurs in men, but may also occur in women.

(f) *Ringworm*. A skin infection caused by certain dermatophytic fungi.

§ 333.210 Antifungal active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

- (a) Clotrimazole 3 percent.
- (b) Haloprogin 1 percent.
- (c) Miconazole nitrate 2 percent.
- (d) Povidone-iodine 10 percent.
- (e) Tolnaftate 1 percent.

(f) Undecylenic acid, calcium undecylenate, copper undecylenate, and zinc undecylenate may be used individually or in any ratio that provides a total undecylenate concentration of 10 to 25 percent.

§ 333.250 Labeling of antifungal drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antifungal."

(b) *Indications*. The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1)(i) of this section and may contain the additional phrase listed in

paragraph (b)(1)(ii) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing any ingredient identified in § 333.210 labeled for the treatment of athlete's foot, jock itch, and ringworm*. (i) (Select one of the following: "Treats," "For the treatment of," "For effective treatment of," "Cures," "For the cure of," "Clears up," or "Proven clinically effective in the treatment of") (select one condition from any one or more of the following groups of conditions:

(A) "Athlete's foot," athlete's foot (dermatophytosis)," "athlete's foot (tinea pedis)," or "tinea pedis (athlete's foot)";

(B) "Jock itch," "jock itch (tinea cruris)," or "tinea cruris (jock itch)"; or

(C) "Ringworm," "ringworm (tinea corporis)," or "tinea corporis (ringworm).")

(ii) In addition to the information identified in paragraph (b)(1)(i) of this section, the labeling of the product may contain the following statement: (Select one of the following: "Relieves," "For relief of," "For effective relief of," or "Soothes,") (select one or more of the following: "Itching," "scaling," "cracking," "burning," "redness," "soreness," "irritation," "discomfort," "chafing associated with jock itch," "itchy, scaly skin between the toes," or "itching, burning feet").

(2) *For products containing the ingredient identified in § 333.210(e) labeled for the prevention of athlete's foot*. (i) (Select one of the following: "Clinically proven to prevent," "Prevents," "Proven effective in the prevention of," "Helps prevent", "For the prevention of," "For the prophylaxis (prevention) of,"